

Draft Agenda September 20, 2002
Nonprescription Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
Hilton Hotel, Silver Spring Maryland
8727 Colesville Road

Safety Issues related to ASA and NSAIDs

8:00 Call to Order, Introductions

Louis Cantilena, M.D., Ph.D., NDAC Chair

Conflict of Interest Statement

Sandra Titus, Ph.D., Executive Secretary, NDAC

8:15 Welcome and Introduction to Today's Issues

Charles Ganley, M.D., Director, Division of Over-the-Counter Drug Products

Overview of Aspirin and NSAID Labeled Warnings

William Gilbertson, Pharm.D., Associate Director of Drug Monographs, Division of Over-the-Counter Drug Products

8:45 Open Public Hearing – Public Presentations

Rebecca Burkholder, National Consumers League

8:50 FDA Presentations

OTC NSAIDs and ASA GI Bleeding: Analysis of Spontaneous Reports

Joyce Weaver, Pharm.D., Office of Drug Safety

GI Risks of Over-the-Counter NSAID's

Byron Cryer, M.D., University of Texas Southwestern Medical School

OTC NSAIDs and Nephrotoxicity

Juan Carlos Pelayo, M.D., Division of Cardio-Renal Drug Products

NSAIDs and Gastrointestinal and Renal Adverse Effects:

Marie Griffin, M.D., Vanderbilt University, Nashville, Tennessee

9:50 Questions to FDA

10:15 Break

10:30 Open Public Hearing – Industry Presentations

Bayer Presenters– 30 minutes

3 minutes - Introduction

Allen H. Heller, M.D., Bayer Consumer Care Division

10 minutes - Overview of Safety Assessment

Gerald A. Faich, M.D., M.P.H, Consultant, Philadelphia, PA

8 minutes - Comparative Safety of OTC Analgesics

James F. Fries, M.D., Professor of Rheumatology, Stanford School of Medicine, Palo Alto, CA

7 minutes - Risk-Benefit of CV Uses of Aspirin

Charles H. Hennekens, M.D., Dr.P.H, Visiting Professor of Medicine, Epidemiology & Public Health, University of Miami

2 minutes - Conclusions

Allen H. Heller, M.D., Bayer Corporation, Consumer Care Division

11:15 Questions to Bayer

11:30 Wyeth Presenters

5 minutes - Safety/Labeling

Roger G. Berlin, M.D., FACP, FACG , President Global Scientific Affairs

5 minutes - Renal considerations for NSAID's

Domenic A. Sica, M.D., School of Medicine, Medical College of Virginia Commonwealth University, Medicine and Pharmacology

Department of Internal Medicine/Nephrology/Pharmacology & Toxicology

5 minutes - GI/Renal toxicity (adults Vs younger populations)

Philip Walson, M.D., Professor, Pediatric Pharmacology & Pharmacy, University of Cincinnati

5 minutes - Potential toxicity relative to overdose

Richard Weisman, Pharm. D., Director, Florida Poison Control Center – Miami

11:50 Questions to Wyeth Presenters

12:00 McNeil Presenter

5 - Aspirin and Cardio Indications

Eric Jeffrey Topol, M.D., Department of Cardiovascular Medicine, The Cleveland Clinic Foundation

5 - Review of Epidemiological Data on Aspirin and Other NSAID's

Kenneth J. Rothman, DrPH , Professor, Epidemiology & Biostatistics, Boston University School of Public Health

12:10 International Ibuprofen Association

Michael Langman, M.D., University of Birmingham

Nicholas Moore, Professor of Clinical Pharmacology, CHU de Bordeaux, France

12:15 Questions to McNeil and International Ibuprofen

12:30 Lunch

1:30 Committee Discussion

5:00 Approximate time of adjournment